

## **REMARKS**

Applicants will address each of the Examiner's rejections in the order in which they appear in the Office Action.

### **Claim Rejections - 35 USC §102**

In the Office Action, the Examiner rejects Claims 12 and 15-17 under 35 USC §102(e) as being anticipated by Saab (US 5,624,392). This rejection is respectfully traversed.

The present application is directed to a catheter for the delivery of radiation treatment elements to a selected location within the intraluminal passageways. With such a device, there is a heightened concern for safety to prevent any unintended exposure of either the patient or the user to radioactivity. Accordingly, the present application is directed to safeguards to protect the patient and user from unintended or prolonged exposure to radiation.

One of these safeguards is a catheter having first, second, third and fourth lumens, as recited in Claim 12 of the present application. As explained in the specification (e.g. page 5, lns. 21-28; page 26, ln. 12- page 27, ln. 15) and shown in the drawings (see e.g. Figs. 23A, 23B and 24) of the present application, one lumen is sized to slidably receive the treating element for advancing the treating element from the proximal end of the catheter to the distal end of the catheter (and to prevent the treating element from exiting the first lumen to outside the catheter at the distal end of the catheter). By having only one lumen for advancing the treating elements from the proximal end of the catheter to the treatment site at the distal end of the catheter, the amount of radiation given to the patient, where the radiation treatment occurs and the length of exposure of the radiation to the treatment site (i.e. the selected location) can be controlled.

However, once the desired period for treatment (and exposure to radiation) is completed, it is highly desirable to remove the treating elements from the patient's body as quickly as possible. Accordingly, the catheter of the present application was designed with two return lumens in fluid communication with the first lumen at the distal end thereof, to receive the treating element at the distal end and return the treating elements from the distal end of the catheter to the proximal end of the catheter which is outside the patient's body (see e.g. 150 in Figs. 23A and 23B and 158 in Fig. 24; page 26, ln. 12 - page 27, ln. 15). In this way, the treating elements are quickly removed from the body, limiting the patient's exposure to the radiation, especially at non-treatment or non-selected locations.<sup>1</sup>

In contrast to the catheter of the present application, Saab is directed to a heat transfer catheter. With such a catheter, a major concern is that for heat transfer fluid at a different temperature than body temperature (either colder or hotter), at locations distal to the proximal point of the catheter where the fluid is introduced, the temperature of the fluid tends to approach the internal body temperature. Further, any temperature difference, even that at the proximal end, exists for only a relatively short time until the fluid at every point along the catheter is heated or cooled to body temperature, which would render the attempted treatment with such fluid worthless (see e.g. col. 4, lns. 46 - 67). Therefore, it is desirable to have the heat transfer fluid reach the treatment area as quickly as possible before the fluid heats/cools to body temperature. Further, since the fluid quickly heats/cools to internal body temperature after treatment, it is not necessary to quickly remove it from the body.

Accordingly, in the Saab embodiment cited by the Examiner in the Office Action (e.g. Fig.

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<sup>1</sup>There is also a fourth lumen open at the distal end and sized to receive a guidewire.

10, col. 16), there are two lumens (108 and 110) for introducing fluid to the catheter and transferring it to the distal end of the catheter and one fluid outlet lumen (114). This arrangement in the cited reference is also considered advantageous for introducing fluids at different temperatures. Hence, as Saab only has a single return lumen, this reference is very different than the catheter claimed in independent Claim 12 of the present application.

The Examiner also contends that Saab discloses the catheter of dependent Claim 15. Applicants disagree. Claim 15 is directed to a catheter having different stiffness and flexibility at the proximal and distal ends, a smaller cross-sectional shape for the distal end and the distal end of the catheter having a non-circular cross-sectional shape. The Examiner cites Fig. 10 and the discussion at col. 16, lns. 59-67 and col. 17, lns. 1-3 of Saab as showing this feature. However, none of those sections show or suggest that the shape of the catheter is non-circular (see Fig. 10 which is round), as in Claim 15.

Therefore, Saab fails to disclose or suggest the catheter of independent Claim 12 or those claims dependent thereon, and these claims are patentable thereover. Accordingly, it is respectfully requested that this rejection be withdrawn.

#### Claim Rejections - 35 USC §103

##### Claims 13 and 14

The Examiner also rejects Claims 13 and 14 under 35 USC §103(a) as being unpatentable over Saab in view of Machold et al. (US 4,976,720). This rejection is respectfully traversed.

These claims are dependent claims. Therefore, for at least the reasons discussed above for independent Claim 12, these dependent claims are also patentable over the cited references.

Accordingly, it is respectfully requested that this rejection be withdrawn.

Claims 12 and 15-17

The Examiner also rejects Claims 12 and 15-17 under 35 USC §103(a) as being unpatentable over Waksman et al. (US 5,683,345) in view of Saab. This rejection is respectfully traversed.

As explained above, independent Claim 12 is directed to a catheter with four lumens, two of which are return lumens.

In contrast, Waksman only describes a single return lumen 204 (and only 3 lumens in the catheter, not four as recited in Claim 12). See e.g. Col. 17, lns. 30-33 in Waksman. There is nothing in the specification in the reference to indicate that there are two return lumens nor four lumens in all.

Further, as explained above, while Saab discloses 4 lumens, it only discloses a single return lumen. Hence, even if it was proper to combine these two references (which Applicants do not admit), the combination thereof would still fail to disclose or suggest the catheter of independent Claim 12 having two return lumens.

Additionally, as the Examiner admits, Waksman does not teach or suggest the catheter of Claim 15. While the Examiner cites Saab as showing such a catheter, as explained above, Saab fails to disclose a catheter with the features of Claim 15, especially one having a non-circular cross-sectional shape of the distal end of the catheter.

Therefore, it is respectfully requested that this rejection be withdrawn.

### New Claims

Applicants are also adding new dependent Claims 24-27. Please charge our deposit account 50/1039 for any fee due for these new claims.

Claims 24 and 25 are dependent on Claim 15 and are patentable over the cited references for at least the reasons discussed above for Claims 12 and 15.

Claims 26-27 are dependent on Claim 12 and recite that the return lumens have a crescent or semi-crescent shape (as shown in Figs. 23A, 23B and 24 of the present application). It is respectfully submitted that none of the cited references disclose or suggest such shapes for the return lumens.

Accordingly, it is respectfully submitted that these claims are also allowable over the cited references.

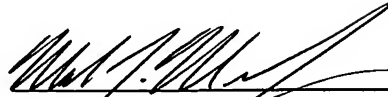
### Conclusion

Therefore, for at least the above-stated reasons, it is respectfully submitted that the present application is in a condition for allowance and should be allowed.

If any fee is due for this amendment, please charge our deposit account 50/1039.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,

  
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